Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13264

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CFSAN

94499

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION (HFD-730)
ROCKVILLE, MD 20857

ADVERSE REACTION REPORT
(Drugs and Biologics)

Form Approved: OMB No. 0910-0230.

FDA CONTROL NO. CFSAN 13264

ACCESSION NO.

I. REACTION INFORMATION

1. PATIENT ID/INITIALS (*In Confidence*) [redacted]

2. AGE 47 YRS.

3. SEX M

4.-6. REACTION ONSET MO. 9 DA. YR. 98

7. DESCRIBE REACTION(S)
MUSCLE & JOINT PAINS

13. RELEVANT TESTS/LABORATORY DATA
Normal LFTs.

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8.-12. CHECK ALL APPROPRIATE:
- ☐ PATIENT DIED
- ☐ REACTION TREATED WITH Rx DRUG
- ☐ RESULTED IN, OR PROLONGED, INPATIENT HOSPITALIZATION
- ☐ RESULTED IN PERMANENT DISABILITY
- ☒ NONE OF THE ABOVE

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (*Give manufacturer and lot no. for vaccines/biologics*)
OTC SUPPLEMENTS - See list

15. DAILY DOSE

16 ROUTE OF ADMINISTRATION P.O

17. INDICATION(S) FOR USE

18. DATES OF ADMINISTRATION (*From/To*)

19 DURATION OF ADMINISTRATION

20. DID REACTION ABATE AFTER STOPPING DRUG? 5
☒ YES ☐ NO ☐ NA

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? N/A
☐ YES ☐ NO ☒ NA

III. CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (*Exclude those used to treat reaction*)
1 MA HUANG
2 GUARANA EXTRACT
3 Garcinia Cambrozia - Hydroxy citrate
4 Chromium
5 L Carnitine Potassium Mg PO4

23. OTHER RELEVANT HISTORY (*e.g. diagnoses, allergies, pregnancy with LMP, etc.*)
REC'D.

IV. ONLY FOR REPORTS SUBMITTED BY MANUFACTURER

24. NAME AND ADDRESS OF MANU [redacted] Code)
MEDWATCH CTU

24a. IND/NDA. NO. FOR SUSPECT DRUG
ob

24b MFR. CONTROL NO.

24c. DATE RECEIVED BY MANUFACTURER

24d. REPORT SOURCE (*Check all that apply*)
☐ FOREIGN ☐ STUDY ☐ LITERATURE
☐ HEALTH PROFESSIONAL ☐ CONSUMER

25 15 DAY REPORT?
☐ YES ☐ NO

25a. REPORT TYPE
☐ INITIAL ☐ FOLLOWUP

V. INITIAL REPORTER (*In confidence*)

26.-26a. NAME AND ADDRESS OF REPORTER (*Include Zip Code*)
[redacted]

26b. TELEP

26c. HAVE YOU ALSO REPORTED THIS REACTION TO THE MANUFACTURER?
☐ YES ☒ NO

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26d. ARE YOU A HEALTH PROFESSIONAL?
☒ YES ☐ NO

Submission of a report does not necessarily constitute an admission that the drug caused the adverse reaction.

NOTE: Required of manufacturers by 21 CFR 314.80

FORM FDA 1639 (7 86) PREVIOUS EDITION MAY BE USED

CTU 94499

Adverse Event Questionnaire

Complaint Number: 13264 **Investigator:** Lincoln, Darla

Consumer Information

Date of Report: 11/16/98 MM/DD/YY

Initial Report Source: ☐ORA Consumer Injury
☐Telephone ☐Correspondence ☒MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted] Gender: ☐F ☒M Age: 47

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other _____ ☐9-Unknown

Information on Adverse Event

Date of Adverse Event: 9-98 to 11/98
Previous Adverse Effects to Product Type: ☐Yes ☒No

Give the site of consumption/ingestion (e.g. home, restaurant, office): home

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): Symptoms Muscle Pain followed by Joint Pain Starting in arms. Reaction Started down after use of Product.
How long did the symptoms last? Varied Few minutes to hours.
Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.). Normal Dosage 1-3 Capsules Twice Daily Orally

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: only Med. Take at time of event.
Did event abate after use of suspected product stopped or dose reduced: ☒Yes ☐No ☐Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☒No ☐Unknown ☐Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No
Give health care provider's name, address and telephone number:
Dr [redacted]

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist
☐Other (specify) _____

What medical tests were performed and what were the results? General Medical exam EKG
What was the medical diagnosis? Reaction to Supplement Patent was taking
What treatment(s) was given (e.g., drugs, other)?
Stop Taking Product Tylenol for Pain.

Were there any preexisting condition(s)/treatment(s)?
(If YES, list them including allergies, and chronic diseases): ☐Yes ☒No

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Product Category

1. Adverse event attributed to:
☐**Medical Food** (under medical supervision) ☐**Infant Formula**
☒**Dietary Supplement** (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
☐**Other** (traditional food) _____

Other Product Problems
2. ☐Foreign Object
(specify):_____

3. ☐Other (specify):
_____

Information on Suspected/Alleged Product

Give the product name and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):
Diet Fuel W/Citra max; TWIN labs - MFG. Dosage 1-3 capsules Twice Daily mid morning & mid Afternoon

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):
☐Check here if ingredients are unknown
Ma Huang 334mg; Guarana Extract 909mg; Garcinia Cambogia - Hydroxycitrate 500mg; Chromium Extract 200 Mcg; L-Carnitine 100mg; Potassium & Magnesium phosphate 100mg

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below:

☐Aspartame
☐Monosodium Glutamate
☐Sulfite
☐Other_____
☐Unknown
☐Color Additive (please specify) _____

Is the product label available, if yes submit a quality copy along with this questionnaire: ☐Yes ☒No ☐Unknown
Product Sample Available: ☐Yes ☒No ☐Unknown

Outcome Attributed to Adverse Event:
(If yes, include pertinent medical records)

Death: ☐Yes ☒No

Life-Threatening: ☐Yes ☒No

Hospitalization: ☐Yes ☒No (if YES, indicate if initial or prolonged) _____

Required intervention to prevent permanent impairment/damage: ☐Yes ☒No

Did the adverse event result in a congenital anomaly: ☐Yes ☒No

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